

## **REMARKS**

Claims 23-25, 28-41 and 44-58 are pending in this application. Claims 23, 25, 37, 39, 41 and 48-57 have been withdrawn and are hereby cancelled without prejudice and for reasons unrelated to patentability. Applicant reserves the right to prosecute these claims in another application.

Claims 24, 28 to 36, 38, 40, 44 to 47 and 58 are the subject of the following rejections.

Applicant traverses each rejection for at least the following reasons:

### **35 U.S.C. 102**

#### **Limtrakul**

The Examiner rejected claims 24, and 28 to 35 under 35 U.S.C. § 102(b) as being anticipated by Limtrakul. Applicant traverses this rejection for at least the following reasons.

The Examiner commented that “the reference clearly teaches administration of the composition to a mammalian cell.” The composition in claims 24, and 28 to 35 is “soybean milk containing soybean trypsin inhibitor” (“STI.”) Animals cannot digest soybean milk with soybean trypsin inhibitor. (See Martin Declaration, ¶ 5, submitted with the March 7, 2002 response) Nutritionally used soy products must have STI inactivated. (Martin Declaration, ¶ 6) Limtrakul studied 28 mice who were fed a diet soybean protein isolate with or, in a separate group, without soybean milk protein (Limtrakul p. 1591-1592). The Examiner noted that “[Limtrakul] obviously administered the soybean milk to the mice,” however, what is relevant is how it was administered. Applicant’s invention used soybean milk with STI, which cannot be digested, but Limtrakul’s mice ingested soybean milk, so therefore it cannot anticipate Applicant’s invention. Since the mice were able to eat this diet, the STI must have been

deactivated and therefore, Limtrakul does not anticipate these claims. Applicant respectfully asserts that this rejection has been overcome.

Kosaka U.S. Patent No. 4,477,434 ("Kosaka")

The Examiner rejected claims 24, 28 to 36, 38, 40, 44 to 47 and 58 under 35 U.S.C. § 102(b) as being anticipated by Kosaka. Applicant traverses this rejection for at least the following reasons.

Applicant made an inadvertent typographical error in its October 8, 2002 response. Kosaka teaches the use of papain, which is a cystein protease, not a serine protease. See Vernet T, et al., Structural and Functional Roles of Asparagine 175 in the Cysteine Protease Papain, J. Biol. Chem. 270: 28, 16645-52, July 14, 1995, and Schirmeister T, New Peptidic Cysteine Protease Inhibitors Derived from the Electrophilic Alpha-amino Acid Aziridine-2,3-dicarboxylic acid, J. Med. Chem., 42: 4, 560-72, Feb. 25, 1999 (copies of which were attached to the October 8, 2002 response).

Kosaka teaches the use of papain and citric acid. Applicant claims the use of "soybean milk containing soybean trypsin inhibitor" (as is noted by the Examiner). Papain, which is required by Kosaka, is not soybean milk nor a soybean trypsin inhibitor. Citric acid, required in Kosaka, is not a limitation of Applicant's claims. Therefore, Kosaka does not teach serine protease nor soybean milk containing STI, and is missing this element of Applicant's claim.

Even when Kosaka mentions that "food and beverage of the present invention can be in a wide variety of forms, such as . . . soybean milk," (Col. 2, lines 43-47) the soybean milk does not contain soybean trypsin inhibitor, as claimed by Applicant. Soybean milk, which is a beverage, cannot have STI because animals cannot digest STI, and will suffer gastrointestinal problems, if

STI is present. The Examiner notes Kosaka's medicinal uses. This is irrelevant; these other uses are not dependent on STI, since it cannot be present in Kosaka's digestible soymilk.

Therefore, since Kosaka is missing soybean milk containing soybean trypsin inhibitor and cannot anticipate the claims, Applicant respectfully asserts that this rejection has been overcome.

Katsumi JP 62036304 ("Katsumi")

The Examiner rejected claims 24, 28 to 36, 38, 40, 44 to 47 and 58 under 35 U.S.C. § 102(b) as being anticipated by Katsumi. Applicant traverses this rejection for at least the following reasons.

Applicant attaches a copy of the Katsumi reference fully translated as Exhibit A. Applicant reasserts its argument from the October 8, 2002 response. Katsumi teaches the use of soybean milk, which was originally used for consumption, as a topical application. Soybean milk (as used in Katsumi) can be treated with salt and heat to yield "cheese-like tofu," and such soybean milk was consumed prior to Katsumi, who recognized its use topically. See Katsumi, page 2. However, soybean milk, which has been processed for consumption such as that in Katsumi, has the STI and BBI activity eliminated, since these proteins inhibit digestion and result in diarrhea (see Declaration of Katharine Martin, paragraph 4 and 6, submitted with the previous response and a copy of which is attached hereto as Exhibit B). The present invention requires that STI and BBI activity be retained, active and non-denatured (see Declaration of Katharine Martin, paragraph 3), which would prevent the consumption of the composition used in the present invention. Katsumi is not a viable reference because unlike Applicant's invention, Katsumi's composition is fit for animal digestion. The Katsumi reference does not have the

same composition applied in the same way as that claimed, as is readily apparent in this response. Therefore, Applicant respectfully asserts that this rejection is overcome.

Application No. 09/110,409

The Examiner has provisionally rejected claims 24, 28-36, 38, 40, 44-47 and 58 under 35 USC § 102(e) as being anticipated by copending Application No. 09/110,409 (“’409 Application”). Inventors Miri Seiberg and Stanley Shapiro were the inventors for both the claimed invention in the relevant claims and the invention disclosed, but not claimed in the 09/110,409 application, and the ’409 Application is therefore not the invention “by another.” (See Seiberg and Shapiro Declaration executed in counterparts attached as Exhibit C).

Limtrakul taken with Kosaka or Katsumi

The Examiner has rejected claims 24, 28-36, 38, 40, 44-47 and 58 under 35 USC § 103 as being unpatentable over Limtrakul taken with Kosaka or Katsumi. Applicant reasserts its arguments above and respectfully traverses this rejection for at least the foregoing and following reasons.

Limtrakul does not teach the use of “soybean milk containing soybean trypsin inhibitor.” The composition used by Limtrakul is used in a dietary manner, whereas Applicant’s claimed “soybean milk containing soybean trypsin inhibitor,” would not be digestable by animals, including humans. Further, many of Applicant’s claims require topical application of the composition, and Limtrakul does not apply soybean milk with STI topically.

Neither Kosaka nor Katsumi teach the use of soybean milk with STI. Kosaka uses a cysteine protease, and citric acid, but not soybean milk with STI. Katsumi teaches a topical use of nutritional soybean milk (which is by definition digestible), which is distinctly different from

soybean milk with STI, which is not digestible and causes gastrointestinal problems upon ingestion (as mentioned above and in the Martin Declaration).

Neither combination of Limtrakul and Kosaka or Katsumi meets all of the limitations of Applicant's claims and therefore, Applicant believes that this rejection is overcome.

#### Double Patenting

The Examiner provisionally rejected claims 24, 28-36, 38, 40, 44-47 and 58 over claims 1-60 of Application No. 09/110,409. Applicant notes that Application No. 09/110,409 has not yet issued as a patent. In the event the patent does issue, Applicant will file an appropriate terminal disclaimer.

#### CONCLUSION

Applicant respectfully asserts that the application is in condition for allowance.

Reconsideration and the early issuance of a Notice of Allowance are requested.

If the Examiner has any outstanding issues, kindly contact the undersigned to set up an interview for the purpose of resolving these issues.

#### Authorization of Deposit Account

The Commissioner is hereby authorized to charge any fees or credit any overpayment, to Deposit Account 18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire

prosecution of this application.

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